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DEC 31 2003

**510(k) Summary**  
**AMS Large Pore Polypropylene Mesh**

**510(k) Number** \_\_\_\_\_

**Date of Summary Preparation:**  
November 17, 2003

**Submitter/Contact Person:**

Elsa A. Linke  
Regulatory Affairs Specialist  
American Medical Systems  
10700 Bren Rd. W  
Minnetonka, MN 55343

Phone: (952) 930-6000  
Fax: (952) 930-6496

**Device Name and Classification:**

Trade Name: AMS Large Pore Polypropylene Mesh  
Common/Usual Name: Surgical Mesh  
Classification Name: Surgical Mesh, polymeric  
Product Code: O T P, O T O  
Classification: Class II

**Manufacturing Location:**

American Medical Systems, Inc.  
10700 Bren Rd. West  
Minnetonka, MN 55343

**Predicate Devices:**

Gynemesh Prolene Soft Mesh – K013718  
Ethicon Prolene Soft Mesh - K001122  
AMS Sacral Colpopexy Sling – K010931

**Indications for Use:**

The AMS Large Pore Polypropylene Mesh is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

**Device Description:**

The AMS Large Pore Polypropylene Mesh is a knitted mesh of polypropylene fibers. The mesh can be cut to any desired shape or size and resists unraveling.

**Summary of Testing**

The material used in the AMS Large Pore Polypropylene Mesh has been demonstrated to be biocompatible.

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In addition, the AMS Large Pore Polypropylene Mesh has been tested for a variety of mechanical characteristics in accordance with FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh and has been shown to be equivalent to the listed predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Ms. Elsa A. Linke  
Regulatory Affairs Specialist  
American Medical Systems  
10700 Bren Road, West  
MINNETONKA MN 55343

SEP 28 2012

Re: K033636  
Trade/Device Name: AMS Large Pore Polypropylene Mesh  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
Product Code: OTP, OTO  
Dated: November 17, 2003  
Received: November 19, 2003

Dear Ms. Linke:

This letter corrects our substantially equivalent letter of December 31, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

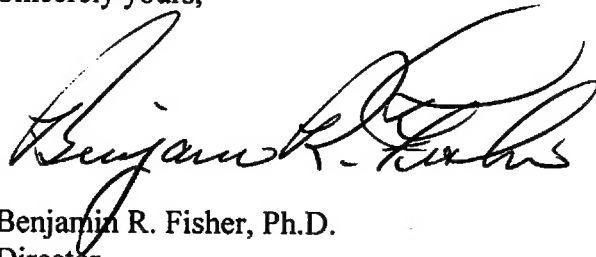
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher". The signature is fluid and cursive, with the first name "Benjamin" being the most prominent part.

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

K033636

INDICATIONS FOR USE ENCLOSURE

510(k) Number: \_\_\_\_\_

Device Name: AMS Large Pore Polypropylene Mesh

**Indications for Use:** The AMS Large Pore Polypropylene Mesh is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

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